

### REMARKS

Claims 1-34 are in the case. Claim 1 is amended herein. The remaining claims are unchanged.

Claims 1-7, 9, 15 and 27-34 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/00712 (Chandler '712), and claims 16-36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Chandler. These rejections are respectfully traversed.

As discussed in Applicants' previous response, in one aspect, recited in claims 1 and 2, Applicants' invention features a device for use in the collection and testing of a sample, including a sample collection device and a housing having an internal recess. The housing is adapted to receive at least a portion of the sample collection device in the internal recess, and to shield a sample collected on the sample collection device. The housing is also adapted to receive an insertable testing element so that, on insertion of the testing element into the housing, the testing element is in liquid-conductive communication with a sample collected on the sample collection device. Because the housing is adapted to receive at least a portion of the sample collection device in the internal recess and to shield the sample, and because the housing is adapted to later receive an insertable testing element, a sample can be collected in one location and/or at one time, and tested at a different location and/or a later time by inserting the insertable testing element at that location/time (see, e.g., p. 4, lines 17-20, p. 5, lines 3-4, p. 6, lines 19-25, and p. 11, lines 23-25 of Applicants' specification). Accordingly, sample collection may be performed at locations where laboratory facilities and skilled personnel are unavailable (see, e.g., Applicants' specification, p. 8, lines 8-10 and the paragraph bridging pp. 8 and 9.) For example, in some cases a patient may obtain a sample in his or her home, and then send the sample to a remote location for centralized test development, e.g., a location where more controlled test development is possible. Centralized test development also opens up the potential for automated test development and instrument reading.

In contrast, the test devices disclosed by Chandler '712 include an integral immuno-chromatographic test strip permanently disposed within the device, e.g., by attachment to one of

the panels of the housing (see, e.g., p. 8, lines 26-27; page 10, lines 25-27). This test strip is not "insertable," nor is the housing adapted to receive an insertable testing element. Immuno-chromatographic test strips are subject to rapid degradation in the presense of moisture. Thus, the devices described in Chandler '712 must be issued and stored in a desiccated environment until opened and then immediately used, limiting the use of these devices to "Point of Care" applications in which tests are developed shortly after sample collection and typically at the site of sample collection.

In another aspect, recited in claim 16, Applicants' invention features a method for the identification of an analyte of interest in a sample, including, *inter alia*, "(c) subsequently inserting an insertable testing element into the housing such that the testing element is in liquid-conductive communication with the sample."

As discussed above, Chandler '712 does not contemplate inserting an insertable testing element into the housing. Thus, the claimed method, like the claimed device, is fundamentally different from that of Chandler '712.

In view of the above remarks, it is respectfully submitted that Chandler '712 neither anticipates nor renders obvious Applicants' claimed invention.

Claims 10-13 have been rejected as unpatentable over Chandler '712 in view of Kang. Claims 8 and 14 have been rejected as unpatentable over Chandler '712 in view of Kang and further in view of U.S. Patent No. 6,165,416 (Chandler '416).

The secondary references cited by the Examiner do not supply what is lacking in Chandler '712. Thus, claims 8 and 10-14 are patentable for at least the reasons discussed above with respect to claims 1 and 2.

Enclosed is a \$55.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 13521-002001.

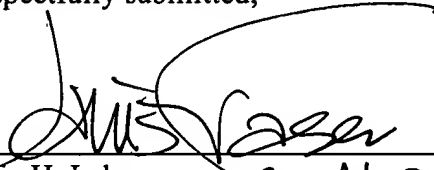
Applicant : Howard M. Chandler et al.  
Serial No. : 09/936,452  
Filed : September 12, 2001  
Page : 11 of 11

Attorney's Docket No.: 13521-  
002001 / 2453801/PP9157/99-JMS

Respectfully submitted,

Date:

April 14, 2004

  
Celia H. Leber  
Reg. No. 33,524

Reg No 34,819

Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110-2804  
Telephone: (617) 542-5070  
Facsimile: (617) 542-8906